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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,719	03/21/2002	Armin Johannes Becker	13390.2USWO	8053

23552 7590 08/17/2004

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EXAMINER
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SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/018,719	<b>Applicant(s)</b> BECKER ET AL.	
	<b>Examiner</b> Christine J. Saoud	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-11 and 16-18 are canceled and claim 12 has been amended in the paper filed 27 May 2004. Claims 12-15 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 27 May 2004 have been fully considered but they are not deemed to be persuasive.

### ***Claim Rejections - 35 USC § 102***

Claims 12-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by SPENCER et al. (WO 98/42361).

Applicant argues that Spencer's disclosure "to neurogenic erectile dysfunction precludes a finding of anticipation, as that element is not an aspect of the claim". However, the instant claim must be given its broadest, reasonable interpretation. Claim 12 requires (1) administration of an effective amount of growth hormone (2) to a patient with sexual functional disorder (3) wherein the disorder is manifested by lack or loss of libido, problems relating to orgasms, insufficient lubrication, or erectile dysfunction (4) wherein insufficient increase in hGH concentration occurs during sexual stimulation or a hGH deficiency exists. Therefore, there are 4 limitations of the claims. Spencer et al. meet these 4 limitations in that Spencer teaches administration of growth hormone (1) for the treatment of sexual functional disorder in a patient (2) wherein the patient has

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erectile dysfunction (3) and wherein the patient has decreased hGH (4). The fact that Spencer's patient population also has neurogenic erectile dysfunction is irrelevant to the issue of anticipation because these patients are not specifically excluded from the claims and the claims use the phrase "comprising", meaning that the claims are open to other elements.

Applicant argues that "there is no indication that the nerve damage is a result of either an hGH deficiency or due to an insufficient increase in hGH concentration during sexual stimulation" (see page 4 of the response). However, Spencer et al. do not need to show this to anticipate the claims; rather, Spencer et al. claims administration for a disorder as a result of aging and decreased hGH is a result of aging. Therefore, the recitation that GH be administered for a disorder as the result of aging inherently meets the limitation of GH deficient because aged individuals are characterized by being GH deficient.

Applicant continues at page 4 of the response to address Spencer's treatment of parasympathetic nerve damage. However, as mentioned previously, the additional condition of the patients of Spencer does not negate the anticipation of the instant claims because the claims contain open language of comprising and therefore, would not exclude additional elements in the art.

Applicant again argues that claim 12 recites "wherein insufficient increase in hGH concentration occurs during sexual stimulation or a hGH deficiency exists". However, this limitation is met by Spencer in the teaching of administration for a disorder as a result of aging since decreased hGH occurs with aging (i.e. hGH deficiency).

Applicant argues that Spencer discloses different mechanisms of action which differentiate from the claimed subject matter. However, the claims are directed to a method of treatment, wherein the prior art meets each limitation of the claim. Therefore, disclosure or discussion of different mechanisms of action are irrelevant, since the prior art meets the limitations of the claims. The disclosure of Spencer may be "narrow", but since the instant claims are "broad", they are anticipated by the narrow disclosure of Spencer et al., absent evidence to the contrary.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

